

UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA

\* \* \*

TAMMI BRANDT,

Plaintiff,

v.

MEDTRONIC, INC., et al.,

Defendants.

Case No. 2:14-cv-01112-MMD-NJK

ORDER

(Def.'s Motion to Dismiss – dkt. no. 26.)

**I. SUMMARY**

Plaintiff asserts claims for injuries resulting from implantation of a medical device. Before the Court is Defendant Medtronic, Inc.'s Motion to Dismiss ("Motion") (dkt. no. 26). The Court has reviewed Plaintiff Tammi Brandt's response (dkt. no. 28) and Medtronic's reply brief (dkt. no. 29). For the reasons discussed below, the Motion is granted; and Plaintiff is granted leave to amend.

**II. BACKGROUND**

In 2000, Medtronic developed the Enterra Therapy System ("the Device" or "the Enterra Device"), a medical device designed to treat gastroparesis, a stomach condition that leads to chronic nausea and vomiting. (Dkt. no. 1 at 7.) Plaintiff, who suffers from gastroparesis, had the Device implanted in May 2009. (*Id.* at 8.) Plaintiff has since suffered pain, nervous system damage, and additional problems with her digestive system because, she claims, the implanted Device has "broken, malfunctioned or otherwise failed." (*Id.*) Plaintiff alleges that her problems with the Device are the result of the Device's "defective design, warnings, construction and unreasonably dangerous

1 character.” (*Id.*) She claims that Defendant concealed these defects; had she been  
2 aware of them, she would not have consented to having the Device implanted. (*Id.*)

3 Plaintiff initiated this lawsuit in Nevada state court in June 2014, asserting claims  
4 for negligence, strict products liability, inadequate warning, breach of express warranty  
5 and the implied warranty of merchantability, and negligent and intentional  
6 misrepresentation. (*Id.* at 9-17.) Medtronic learned of the filing before being served with  
7 the Complaint; it removed the action to this Court on July 8, 2014, on the basis of  
8 diversity jurisdiction. (*Id.* at 2-3.) Medtronic moved to dismiss the Complaint in April  
9 2015. (Dkt. no. 26.)

### 10 **III. LEGAL STANDARD**

11 A court may dismiss a plaintiff’s complaint for “failure to state a claim upon which  
12 relief can be granted.” Fed. R. Civ. P. 12(b)(6). A properly pleaded complaint must  
13 provide “a short and plain statement of the claim showing that the pleader is entitled to  
14 relief.” Fed. R. Civ. P. 8(a)(2); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).  
15 While Rule 8 does not require detailed factual allegations, it demands more than “labels  
16 and conclusions” or a “formulaic recitation of the elements of a cause of action.” *Ashcroft*  
17 *v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555). “Factual  
18 allegations must be enough to raise a right to relief above the speculative level.”  
19 *Twombly*, 550 U.S. at 555. Thus, “[t]o survive a motion to dismiss, a complaint must  
20 contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is  
21 plausible on its face.’” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570).

22 In *Iqbal*, the Supreme Court clarified the two-step approach district courts are to  
23 apply when considering motions to dismiss. First, a district court must accept as true all  
24 well-pleaded factual allegations in the complaint; however, legal conclusions are not  
25 entitled to the assumption of truth. *Id.* at 678. Mere recitals of the elements of a cause of  
26 action, supported only by conclusory statements, do not suffice. *Id.* Second, a district  
27 court must consider whether the factual allegations in the complaint allege a plausible  
28 claim for relief. *Id.* at 679. A claim is facially plausible when the plaintiff’s complaint

1 alleges facts that allow a court to draw a reasonable inference that the defendant is  
 2 liable for the alleged misconduct. *Id.* at 678. Where the complaint does not “permit the  
 3 court to infer more than the mere possibility of misconduct, the complaint has alleged —  
 4 but it has not ‘shown’ — ‘that the pleader is entitled to relief.’” *Id.* at 679 (alteration  
 5 omitted) (quoting Fed. R. Civ. P. 8(a)(2)). When the claims in a complaint have not  
 6 crossed the line from conceivable to plausible, the complaint must be dismissed.  
 7 *Twombly*, 550 U.S. at 570. A complaint must contain either direct or inferential  
 8 allegations concerning “all the material elements necessary to sustain recovery under  
 9 some viable legal theory.” *Id.* at 562 (quoting *Car Carriers, Inc. v. Ford Motor Co.*, 745  
 10 F.2d 1101, 1106 (7th Cir. 1984)).

#### 11 **IV. ANALYSIS**

12 The Motion raises two theories for dismissal: first, Plaintiff’s claims are entirely  
 13 preempted by federal law, and second, the Complaint is inadequately pleaded. (Dkt. no.  
 14 26 at 2.) The gist of the preemption argument is that the Device is heavily regulated  
 15 under the premarket approval (“PMA”) process of the Food and Drug Administration  
 16 (“FDA”), such that state law claims that exceed or differ from the governing federal laws  
 17 must yield to the federal regulatory scheme.<sup>1</sup> Because the Court finds that the  
 18 preemption arguments are dispositive of the Motion, the Court will not reach the  
 19 sufficiency of the pleadings.

#### 20 **A. Background on Federal Regulation of Medical Devices**

21 The 1976 Medical Device Amendments (“MDA”) to the Federal Food, Drug, and  
 22 Cosmetic Act (“FDCA”) created an express preemption clause to facilitate better federal

23 ///

24 ///

---

25 <sup>1</sup>Medtronic asks the Court to take judicial notice of several documents relating to  
 26 the Device’s regulation by the FDA. (Dkt. no. 27.) Courts may “take judicial notice of  
 27 matters of public record outside the pleadings’ and consider them for purposes of [a]  
 28 motion to dismiss.” *Mir v. Little Co. of Mary Hosp.*, 844 F.2d 646, 649 (9th Cir. 1988)  
 (quoting *MGIC Indem. Corp. v. Weisman*, 803 F.2d 500, 504 (9th Cir. 1986)).  
 Medtronic’s documents are online public records of the Device’s PMA process. (See dkt.  
 no. 27.) The Court will consider them in analyzing the Motion.

1 regulation of complex medical devices. *Riegel v. Medtronic*, 552 U.S. 312, 315-16  
2 (2008). The clause prohibits any state (and any political subdivision of a state) from:

3       establish[ing] or continu[ing] in effect with respect to a device intended for  
4       human use any requirement (1) which is different from, or in addition to,  
5       any requirement applicable under this chapter to the device, and (2) which  
6       relates to the safety or effectiveness of the device or to any other matter  
7       included in a requirement applicable to the device under this chapter.

8 21 U.S.C. § 360k(a). The MDA additionally created a multi-level regulatory scheme that  
9 classifies medical devices into three categories: Class I, Class II, and Class III. *Riegel*,  
10 552 U.S. at 316-17; see 21 U.S.C. § 360c. The Enterra Device falls into Class III, the  
11 most stringently regulated category. (See dkt. no. 27-5 at 2-4 (approving the Device for  
12 commercial distribution after a premarket analysis).) “If a device cannot be determined to  
13 provide a reasonable assurance of safety and effectiveness under Class I or II controls  
14 and is either marketed as a life-supporting device or may cause an unreasonable risk of  
15 illness or injury, it is a Class III device.” *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1226  
(9th Cir. 2013) (en banc).

16       Class III devices are subjected to a “rigorous” PMA process, during which the  
17 FDA reviews, among other documents, reports about the device’s safety, a full  
18 documentation of the device’s components, a description of the device’s manufacturing  
19 and processing methods and facilities, and samples of the device and its labeling.  
20 *Riegel*, 552 U.S. at 318. “The FDA spends an average of 1,200 hours reviewing each  
21 [premarket] application.” *Id.* After receiving premarket approval, “the MDA forbids the  
22 manufacturer to make, without FDA permission, changes in design specifications,  
23 manufacturing processes, labeling, or any other attribute, that would affect safety or  
24 effectiveness.” *Id.* at 319. PMA recipients also retain an ongoing obligation to update and  
25 inform the FDA of certain incidents involving a device’s safety. *Id.* at 319-20.

26       The FDA’s PMA review of the Enterra Device proceeded through a humanitarian  
27 device exemption (“HDE”), which applies to devices designed to treat or diagnose  
28 conditions that affect “fewer than 4,000 individuals in the United States per year.” (Dkt.

1 no. 27-4 at 2.) The HDE review process is similar to the PMA process, but HDE  
2 alleviates the need to demonstrate scientifically “that the device is effective for its  
3 intended purpose.” (*Id.*) Before approving a device through an HDE review, the FDA  
4 must find that “the device will not expose patients to an unreasonable or significant risk  
5 of illness or injury and the probable benefit to health from the use of the device  
6 outweighs the risk of injury or illness from its use.” 21 U.S.C. § 360j(m)(2)(C). The  
7 Enterra Device received HDE approval in March 2000. (Dkt. no. 27-5 at 2-4.)

8 **B. Express Preemption**

9 In *Riegel*, the Supreme Court held that the MDA’s express preemption provision,  
10 21 U.S.C. § 360k(a), applied to common-law tort claims directed toward a Class III  
11 device. 552 U.S. at 322-25. Because § 360k(a) applies only to “requirement[s]  
12 applicable” to a regulated device, the Court first assessed whether federal regulations  
13 constitute “requirements” that could be displaced by state laws. See *id.* at 321-22. The  
14 PMA process, the Court reasoned, imposes “federal safety review” requirements that are  
15 specific to covered devices; the PMA process therefore “imposes ‘requirements’ under  
16 the MDA.” *Id.* at 322. Next, the Court examined whether common-law tort claims would  
17 qualify as state-level requirements, which are “different from, or in addition to,” the PMA  
18 process, and which “relate[] to the safety or effectiveness of the device.” 21 U.S.C.  
19 § 360k(a); see *Riegel*, 552 U.S. at 323-24. Looking at other statutes’ use of the phrase  
20 “requirement,” the Court concluded that, for § 360k(a) purposes, “a State’s  
21 ‘requirements’ includes its common-law duties.” *Riegel*, 552 U.S. at 324. The Court  
22 therefore affirmed the lower courts’ dismissal of the plaintiffs’ strict liability, implied  
23 warranty, and negligence claims. *Id.* at 320, 330. The Court clarified, however, that  
24 “§ 360k does not prevent a State from providing a damages remedy for claims premised  
25 on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than  
26 add to, federal requirements.” *Id.* at 330.

27 ///

28 ///

1 Here, there is no dispute that the Enterra Device was subjected to a PMA  
2 process, albeit through an HDE.<sup>2</sup> (Dkt. no. 26 at 8; dkt. no. 28 at 3.) In light of the  
3 Device's premarket review, Medtronic insists that § 360k(a) bars Plaintiff's common-law  
4 claims for negligence, strict liability, breach of warranty, and fraudulent  
5 misrepresentation. (Dkt. no. 26 at 8-10.) In each claim, Plaintiff generally asserts that  
6 Medtronic designed, manufactured, produced, and distributed a fundamentally flawed  
7 product, and failed to disclose or accurately represent those flaws to the public. (See dkt.  
8 no. 1 at 9-17.) Plaintiff's negligence claim, for example, alleges that Defendant breached  
9 a duty to exercise reasonable care "in the designing, researching, manufacturing,  
10 marketing, supplying, promoting, sale, quality assurance, quality control, instruction,  
11 warning, distribution and/or recall of the Enterra Device." (*Id.* at 9.) Defendant's failure to  
12 exercise due care began, Plaintiff alleges, "at the earliest date that it became known to  
13 Defendants that the device was, in fact, dangerous and defective." (*Id.*) Plaintiff's strict  
14 products liability claims similarly allege that "[a]t all times relevant herein, the Enterra  
15 Device was designed, manufactured, advertised, promoted, marketed, sold, and/or  
16 distributed by Defendants in an unsafe, defective, and inherently dangerous condition."  
17 (*Id.* at 10; see *id.* at 12 (alleging that despite Defendants' knowledge of the Device's  
18 failure rate, they "failed to give consumers adequate warning of such risks").) Her  
19 warranty claims further suggest that the Device fails to conform to Defendant's promises  
20 of its effectiveness and safety. (*Id.* at 13-14.) Finally, the misrepresentation claims aver  
21 that Defendant misled the public, Plaintiff, and her physicians "regarding the quality,  
22 safety and effectiveness of the Enterra Device." (*Id.* at 15; see *id.* at 16 (alleging that  
23 Defendant intentionally made false statements and concealed knowledge about the  
24 Device's safety).)

---

25  
26 <sup>2</sup>Plaintiff asserts, without citing any legal authority, that the HDE process does not  
27 trigger the preemptive effects of § 360k(a). (Dkt. no. 28 at 3.) But, as Medtronic points  
28 out, the *Riegel* Court explicitly referenced an HDE device as an example of a device  
subject to FDA's premarket approval process. 552 U.S. at 318; (see dkt. no. 29 at 8 n.2).  
Plaintiff's unsupported argument is not persuasive.

1           These common-law allegations fit within the broad preemptive reach of § 360k(a).  
2   See *Riegel*, 552 U.S. at 324. Plaintiff's general assertions stretch from the Device's  
3   inception and design through its manufacturing and distribution — processes that would  
4   be covered and controlled by the HDE approval process. Furthermore, Plaintiff's  
5   allegations that Medtronic misled and failed to warn the public about the Device's safety  
6   issues expand on the FDA's existing PMA protocols for device labeling. See *id.* at 318  
7   ("The premarket approval process includes review of the device's proposed labeling. The  
8   FDA evaluates safety and effectiveness under the conditions of use set forth on the label  
9   . . . and must determine that the proposed labeling is neither false nor misleading.") To  
10   the extent these claims could be read as alleging that Medtronic misled the FDA while  
11   seeking HDE approval, they still warrant dismissal — the Supreme Court has rejected  
12   such "fraud-on-the-FDA" claims as impliedly preempted by the MDA. *Stengel*, 704 F.3d  
13   at 1229 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001)). As  
14   alleged, Plaintiff's common law claims add to, and differ from, the HDE premarket  
15   approval process that applied to the Enterra Device. Federal law therefore preempts  
16   Plaintiff's claims, and dismissal is proper.

### 17           **C.     Parallel State-Law Claims**

18           In opposing the Motion, however, Plaintiff argues that her claims qualify for an  
19   exception to preemption under § 360k(a). Under this logic, Plaintiff's claims suggest that  
20   Medtronic violated Nevada law by withholding information from the FDA after obtaining  
21   PMA of the Enterra Device, or by failing to monitor the product for defects once it was on  
22   the market. (Dkt. no. 28 at 3-4.) Rather than differing from, or adding to, the FDA's PMA  
23   process, these claims run parallel to federal requirements and are not preempted by  
24   § 360k(a). See *Riegel*, 552 U.S. at 330.

25           The Ninth Circuit has determined that a similar failure-to-warn claim brought  
26   under Arizona's negligence laws was not preempted by § 360k(a). *Stengel*, 704 F.3d at  
27   1232-34. There, the claim alleged that the defendant had a continuing duty under federal  
28   law to monitor, discover, and report any problems with an approved medical device to



1 the FDA. *Id.* at 1232. The plaintiffs alleged that the defendant's failure to carry out its  
2 federal duty constituted a breach of "its 'duty to use reasonable care' under Arizona  
3 negligence law." *Id.* Rather than expand or modify an existing federal duty, the Arizona  
4 negligence claim simply sought to hold the defendant accountable under state law for  
5 failing to carry out a federal-law duty — that is, to notify the FDA of "information  
6 'reasonably suggesting' that one of its devices 'may have caused or contributed to a  
7 death or serious injury.'" *Id.* at 1234 (Watford, J., concurring) (alteration omitted) (quoting  
8 21 C.F.R. § 803.50(a)). The Ninth Circuit accordingly held that § 360k(a) did not preempt  
9 the Arizona negligence claim. *Id.* at 1233.

10 As they currently stand, Plaintiff's claims fall short of alleging a state-law claim  
11 that runs parallel to federal requirements. She does allege, however, that Medtronic  
12 "failed to exercise reasonable care" in overseeing "quality assurance [and] quality  
13 control" of the Device. (Dkt. no. 1 at 9.) She further claims that Medtronic withheld known  
14 safety risks from the public. (*Id.* at 15-16.) Plaintiff does not specify when Medtronic  
15 learned of those safety risks — if they arose after the Device's PMA, then Plaintiff may  
16 be able to make out a claim to hold Medtronic accountable under state law for breaching  
17 a parallel duty under federal law. See *Stengel*, 704 F.3d at 1232-34. Because the Court  
18 cannot conclude that Plaintiff would be unable to cure the preemption issues that  
19 currently plague the Complaint, the Court will grant Plaintiff leave to amend.

## 20 **V. CONCLUSION**

21 The Court notes that the parties made several arguments and cited to several  
22 cases not discussed above. The Court has reviewed these arguments and cases and  
23 determines that they do not warrant discussion or reconsideration as they do not affect  
24 the outcome of Medtronic's Motion.

25 It is therefore ordered that Medtronic's Motion to Dismiss (dkt. no. 26) is granted.  
26 If Plaintiff wishes to attempt to cure the preemption issues noted above, she has leave to  
27 file an amended complaint within fourteen (14) days of the date of this Order. Failure to

28 ///



1 file an amended complaint within this deadline will result in dismissal of this action with  
2 prejudice.

3 DATED THIS 31<sup>st</sup> day of March 2016

4  
5 

6 MIRANDA M. DU  
7 UNITED STATES DISTRICT JUDGE  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28